UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

KIMBERLY-CLARK WORLDWIDE, INC., et al.,

Plaintiffs,

v. Case No. 09-C-429

TYCO HEALTHCARE GROUP LP, et al.,

Defendants.

DECISION AND ORDER

This case is presently before me upon Plaintiff Kimberly-Clark's ("K-C") motion for a preliminary injunction to prohibit Defendant Tyco Healthcare Group LP (d/b/a "Covidien") from marketing and selling a line of endotracheal tubes under the "SealGuard" trademark. K-C alleges that the SealGuard products infringe U.S. Patent No. 6,526,977, the rights to which K-C acquired in 2005 from a German company. The parties have had the opportunity to brief the motion and, on June 25, they appeared for a hearing. For the reasons given below, I conclude that the motion for preliminary relief should be denied.

I. Background

A. The '977 Patent

U.S. Patent No. 6,526,977 describes a product known as an endotracheal cuff, which is a sort of thin balloon that anchors endotracheal and tracheostomy tubes in a patient's trachea during long periods of intubation (e.g., intensive care). Among the principal purposes of the cuff is to seal out leakage of secretions into the patient's lungs, which can lead to a fairly common and problematic

onset of pneumonia known as ventilator-associated pneumonia ("VAP"). According to the parties, VAP can be deadly but at a minimum it results in longer hospital stays and markedly increased healthcare costs. Generally speaking, endotracheal cuffs prevent this leakage by inflating and expanding to the width of a patient's trachea, thus forming a tight seal between the breathing tube and the trachea wall.

Some cuffs, known as high pressure, low volume ("HPLV") cuffs, use the pressure of the inflated cuff to press against the tracheal wall and form a tight seal. In order to achieve an optimum seal, however, the pressure is often too high and can cause damage to the trachea. According to the '977 patent, "[w]hen the filling pressure of the cuffed balloon exceeds the blood flow pressure of the vascular bed supplying the film of the mucous membrane, serious structural lesions of the epithelium might ensue." (Col. 1: 31-34.)

Thus, the purpose of the '977 invention was to create a cuff providing an adequate seal but without the risk of damage arising from high cuff pressure. The invention does so by teaching a cuff of a fixed size that is tailored to the patient's trachea. This is known as a high volume, low pressure ("HVLP") cuff. K-C describes the difference as follows: HPLV cuffs are like standard latex balloons, whose size depends on the air pressure inside, whereas the low pressure cuffs are more like Mylar balloons. These will expand until they reach their predetermined and preformed shape, but not any further. The HVLP cuffs are designed to be wider than the patient's trachea, so that when the cuff is inserted and inflated it will expand until it presses lightly against the trachea and then will fold in upon itself, a process K-C describes as "infolding".

Although these kinds of cuffs eliminated the problem resulting from high pressure, the creation of folds proved to be a key problem with HVLP cuffs. If the cuff created vertical "draped"

folds, these could form channels wide enough to conduct secretions into the patient's lungs – the very problem cuffs are designed to solve. In other words, the HVLP cuffs are more porous than HPLV cuffs because the folds resulting from infolding create openings for fluids to pass. The '977 patent is intended to alleviate that problem through the design of the folds themselves. The use of an ultra-thin polyurethane material allows the folds that form to be "self-sealing" folds. In other words, the material is so thin that the walls of the folds will press together and either eliminate any channels or openings that might otherwise conduct fluids or cause any "loops" or other openings to be so small that they do not conduct secretions.

By way of crude analogy, imagine an empty cardboard roll designed to hold paper towels or toilet paper. Suppose that you tried to press such a roll into a lead pipe whose circumference was a half-inch narrower than the roll. It is not difficult to imagine the roll bending in on itself and creating a crease or fold. The roll will generally hold its cylindrical shape (apart from the crease) because that is how it is preformed. The fold created, however, will likely be jagged and imperfect, possibly with loops or other openings, an inevitable result of the relatively thick cardboard from which the roll is made. It is not hard to imagine making a similarly shaped roll out of a much thinner material, such as aluminum foil. The thinner the material is, the more complete or perfect the fold will be, because there is little rigidity or excess material to get in the way of the walls pressing together with they fold in upon themselves. And if one used an ultra-thin material and added air pressure to the inside, it is not hard to envision how the walls of the outer and inner pressure would combine to cause the fold walls to press together and essentially seal themselves or remain extremely narrow. The thinner the material, the more likely it is that the folds become tight creases with very narrow loops or other openings.

The '977 patent describes the process as follows:

> Surprisingly enough, the flow of secretion can be influenced by a specific design of the cuff folding in the area of the loop of the fold, i.e. at the base of the fold. While in the prior art it has so far been assumed that cuffed balloons with a draped fold cannot rest on the trachea in a sufficiently tight manner because of the low filling pressure, the invention shows a method of inhibiting the flow of secretion, the method being employed in the area of the loop of the fold. When the diameter of the loop is sufficiently small at the base of the fold, the free flow of secretion through the loop is inhibited. When the cuff is blocked, the resultant loops at the deep end of the fold can be reduced with respect to their diameter, for instance by selecting the material or the foil thickness, in such a manner that the flow of secretion is decelerated or, ideally, stopped altogether.

(Col. 2: 9-23.)

Claim 1 of the patent sets forth the invention as follows:

> A ventilating device for obturating a patient's trachea as hermetically as possible, comprising a cuffed balloon which 40 blocks the trachea below a patient's glottis, an air tube, the cuffed balloon being attached to the air tube and being sized to be larger than a tracheal diameter when in a fully inflated state and being made of a sufficiently soft, flexible foil material that forms at least one draped fold in the cuffed 45 balloon when fully inflated in the patient's trachea, wherein the at least one draped fold formed has a capillary size which arrests free flow of secretions across the balloon by virtue of capillary forces formed within the fold to prevent aspiration of the secretions and subsequent infections related to secretion aspiration.

(Col. 11: 39-51.)

The '977 patent issued to Dr. Fred Goebel on March 4, 2003. Dr. Goebel sold the ultra-thin-walled cuffs that embodied his patent through a German company he formed named MicroCuff GmbH. K-C acquired the rights to the '977 patent when it purchased MicroCuff GmbH from Dr. Fred Goebel in 2005. (Decl. of Christopher T. La Testa, Exhs. A-C.) K-C has been selling its commercial embodiment of the '977 patent, known as the MicroCuff endotrachial tube, since 2006.

B. Covidien's Endotracheal Cuffs

Covidien (through its predecessors) has been selling endotrachial tubes since at least the mid-1970s. (Decl. of Michael Vannier, ¶ 17.) In fact, Covidien had been selling endotrachial tubes

made with the ultra-thin balloon cuffs manufactured by MicroCuff GmbH under the '977 patent in Europe and other countries since 2004. (La Testa Decl. ¶ 5, Ex. D.) Covidien purchased the patented cuffs under a Supply Agreement with MicroCuff GmbH and sold the endotracheal tubes made with them under its SealGuard brand name. Under its agreement with MicroCuff GmbH, Covidien was granted a non-exclusive and royalty-free license with respect to MicroCuff's intellectual property rights. Covidien later attempted to acquire MicroCuff GmbH when Dr. Goebel indicated his intent to sell the company, but was outbid by K-C. Covidien thereupon arranged to purchase an 18-month supply of cuffs from MicroCuff GmbH before its agreement expired and accelerated its plans to develop a replacement for the cuffs manufactured by MicroCuff. (Pl.'s Ex. 4.)

In late January or early February 2009, Covidien announced its new line of endotracheal tubes with ultra-thin HVLP cuffs. Still sold under SealGuard moniker, the cuffs on Covidien's new line of endotracheal tubes are tapered at an eleven-degree angle, in contrast to the cuffs shown in the figures of the '977 patent, which are generally barrel-shaped or round like a ball. The lower end of the SealGuard cuff is narrower than the patient's trachea, and the upper end is wider. Because of this tapered design, the cuff fits into the trachea like a stopper or a tapered cork. At the point where the tapered cuff is just as wide as the patient's trachea, the cuff forms a seal with the trachea. Covidien calls this a "sealing band" – a narrow point of contact between the cuff and the trachea similar to the seal formed by earlier HPLV cuffs but without the high pressure. Importantly, in this sealing band area, Covidien contends, there are no draped folds at all – the idea is that because the cuff has fit at the precise spot where its width matches the patient's trachea, there is no "infolding" because the cuff width at the sealing band is no wider than the trachea.

The upshot of all this is that the SealGuard products achieve a seal because the tapered shape allows the cuff to match up with the width of the patient's trachea at some discreet point along the taper. At this point, there are no folds at all, and thus no chance of secretion passing through the folds. In a nutshell, Covidien argues that the K-C patent is essentially designed to eliminate the problems associated with the draped folds that form in HVLP cuffs, whereas Covidien's products simply eliminate the folds altogether.

II. Analysis

A. Preliminary Injunction Standards

A party seeking a preliminary injunction must demonstrate that it is reasonably likely to succeed on the merits. It must also show that it is experiencing irreparable harm that exceeds any harm its opponent will suffer if the injunction issues, that it lacks an adequate remedy at law, and that the injunction would not harm the public interest. *Christian Legal Soc'y v. Walker*, 453 F.3d 853, 859 (7th Cir. 2006). "If the moving party meets this threshold burden, the district court weighs the factors against one another in a sliding scale analysis . . . which is to say the district court must exercise its discretion to determine whether the balance of harms weighs in favor of the moving party or whether the nonmoving party or public interest will be harmed sufficiently that the injunction should be denied." *Id.*[1]

B. Likelihood of Success on the Merits

The principal inquiry in most cases involves an assessment of the movant's likelihood of succeeding after a full hearing or trial. "The *sine qua non* of this four-part inquiry is likelihood of

[1]Although the Federal Circuit hears appeals from patent cases, the governing standards are those of the Seventh Circuit. *Mikohn Gaming Corp. v. Acres Gaming, Inc.,* 165 F.3d 891, 894 (Fed. Cir. 1998).

success on the merits: if the moving party cannot demonstrate that he is likely to succeed in his quest, the remaining factors become matters of idle curiosity." *Wine and Spirits Retailers, Inc. v. Rhode Island,* 418 F.3d 36, 46 (1st Cir. 2005). As in many patent cases, success on the merits depends not only on the question of infringement, but on the validity of the underlying patent itself. But the infringement question is the primary inquiry, because if there is no infringement there need not be an assessment of validity. Accordingly, I will address that issue first.

1. Infringement

The parties spend a large portion of their efforts arguing why the Covidien cuffs do, or do not, infringe the '977 patent. But before addressing the '977 patent's applicability to the Covidien products, it is necessary to interpret certain of the patent's claim terms. Much of the debate turns on the length of the draped folds. Covidien argues that these folds, as described in the claims, must extend "from the proximal end to the distal end of the cuffed balloon" (i.e., the top to the bottom). K-C protests that such a limitation is found nowhere in the claim language and notes that at least one of the embodiments shown in the specification does not have folds extending the length of the cuff.

Covidien's argument is based on both the language and purpose of the patent. The key claim language is as follows: "the at least one draped fold formed has a capillary size which arrests free flow of secretions across the balloon by virtue of capillary forces formed within the fold to prevent aspiration . . ." (Col. 11:47-49.) In its brief in opposition to K-C's motion, Covidien focused on the phrase "across the balloon," arguing that this means the fold or folds must extend across the length of the entire cuff. This is shown in Figure 1, for example, where the folds (10) extend the entire length of the cuff. At the hearing, Covidien's infringement argument shifted and it pointed out that

the term "draped" can signify something that extends the entirety of the span covered. Window drapes, for example, generally run nearly the entire height of a room.

In addition, Covidien argues, the entire purpose of the patent is premised on the assumption that the folds extend the entire length of the cuff. If the folds did *not* extend the entire length, there would be no reason to be concerned about secretions passing through because the folds do not even extend that far. The patent's novelty involves ways to overcome the problems associated with folds that would allow passage of secretions *but for* that novelty, which is that the capillary forces formed by narrow folds will "arrest" the secretions. If the folds did not otherwise transmit secretions through the cuff (i.e., because the folds did not extend the length of the cuff), the alleged novelty of creating very narrow folds would not be useful at all. Thus, Covidien argues, if the draped fold or folds described in the claims do not extend the entire length of the cuff, the patent makes no sense.

K-C argues that the claim language merely describes the presence of a "draped fold" without limiting it to a specific length. To import a limitation from the specification or from the more general purpose of the patent would violate a cardinal precept of claim interpretation. *SciMed Life Systems, Inc. v. Advanced Cardiovascular Systems, Inc.*, 242 F.3d 1337, 1340 (Fed. Cir. 2001) (noting that one of the "cardinal sins" of patent law is reading a limitation from the written description into the claims). The use of the term "draped" suggests only that the fold runs lengthwise, like a drape, but it does not imply that the fold must run the entirety of the cuff. Window drapes do not necessarily extend the entire height of a room – they can cover all or only part of a window. The important feature about the term "draped" is that it describes a lengthwise fold, akin to a drape, not that it extends a given length. And although the claim describes the

arresting of secretion flow "across the balloon," it does not contain a requirement that this process occur across the entire length of the balloon.

Moreover, K-C notes, one of the embodiments shows a cuff structure wherein the folds clearly do not extend the length of the balloon. Figure 10, for example, shows an embodiment using two balloons – one called a "tampon balloon" and another called an "air-blocked cuff." When this structure is used, the inner balloon presses the outer balloon so that it meets the patient's tracheal wall. No folds are formed in this section, as shown in Figure 10. Although there are some folds in the tampon balloon structure (5, 24), these are eliminated by the fixing cuff (23). As such, the folds do not extend the entire length of the cuff. As the specification explains, "the tampon balloon complies with the inventive principles governing the design of a sealing and gentle cuffed balloon. The formation of the above-described capillary-like structure is thereby prevented." (Col. 4: 1-4.)

Although Covidien's argument based on the overall purpose of the patent is somewhat persuasive, I am not satisfied that it is enough to allow me to essentially insert an important limitation into the claim language itself. K-C notes that the language itself is silent on the subject, and neither the phrase "across the balloon" nor the term "draped" can reasonably be read as meaning "from the proximal end to the distal end of the balloon." There is certainly no disclaimer or disavowal in either the prosecution history or the specification that would suggest the folds described must be folds that extend the entirety of the cuff. More likely, the phrase "across the balloon" allows for the possibility that some folds might indeed extend the entire length while others will not. And when one of the embodiments shows folds that do not extend the entirety of the cuff, Covidien would need extremely strong evidence to support its contrary claim construction. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996) ("Such an interpretation

is rarely, if ever, correct and would require highly persuasive evidentiary support, which is wholly absent in this case.")

Moreover, I am not persuaded by Covidien's argument that the invention would be rendered useless if the folds did not extend the entire length of the cuff. Of course there is nothing wrong with looking to the purpose of a patent to discern the meaning of claim terms, and such terms must be read in light of the specification. *SciMed Life Systems,* 242 F.3d at 1341. But nothing in the specification suggests that the patent was designed only to prevent secretion flowage through folds that extend the *entire* length of the cuff. Instead, there is a suggestion that *any* penetration of secretion through cuff folds is problematic. For example, if a fold allowed a secretion to travel three-fourths the length of the cuff, it is much easier for that secretion to find its way to the patient's lungs through other channels and folds. Thus, the '977 patent may be useful in arresting the progress of secretions in *any* folds, regardless of whether a given fold extends the entirety of the cuff. Accordingly, I find K-C's position preferable, namely, that the claim language should remain as-is rather than be limited by the proposal Covidien suggests. And because Covidien's claim construction was the premise underlying its argument for noninfringement, it follows that Covidien's cuffs likely infringe the '977 patent.

2. Validity

Covidien also argues that the '977 patent is invalid because it was anticipated by prior art. The validity argument was not a centerpiece of Covidien's defense, and so I address its arguments only briefly.

Patents are presumed valid. When a challenge is made to a patent's validity at the preliminary injunction stage, courts must be especially mindful of the presumption of validity

because the validity question has likely not been fully explored at the preliminary stage. The Federal Circuit has recently taken the opportunity to explain the proper considerations at some length:

> Before trial, when the question of validity arises at the preliminary injunction stage, the application of these burdens and presumptions is tailored to fit the preliminary injunction context. To begin, the patent enjoys the same presumption of validity during preliminary injunction proceedings as at other stages of litigation. Thus, if a patentee moves for a preliminary injunction and the alleged infringer does not challenge validity, the very existence of the patent with its concomitant presumption of validity satisfies the patentee's burden of showing a likelihood of success on the validity issue.
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> If, instead, the alleged infringer responds to the preliminary injunction motion by launching an attack on the validity of the patent, the burden is on the challenger to come forward with evidence of invalidity, just as it would be at trial. The patentee, to avoid a conclusion that it is unable to show a likelihood of success, then has the burden of responding with contrary evidence, which of course may include analysis and argument.
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> While the evidentiary burdens at the preliminary injunction stage track the burdens at trial, importantly the ultimate question before the trial court is different. As this court explained in *New England Braiding Co. v. A.W. Chesterton Co.*, the trial court [ruling on a motion for preliminary relief] "does not resolve the validity question, but rather must . . . make an assessment of the persuasiveness of the challenger's evidence, recognizing that it is doing so without all evidence that may come out at trial." 970 F.2d 878, 882-83 (Fed. Cir. 1992). Instead of the alleged infringer having to persuade the trial court that the patent is invalid, at this stage it is the patentee, the movant, who must persuade the court that, despite the challenge presented to validity, the patentee nevertheless is likely to succeed at trial on the validity issue.

Titan Tire Corp. v. Case New Holland, Inc., – F.3d –, 2009 WL 1542401, 3 (Fed. Cir. 2009) (most citations omitted).

Covidien's anticipation argument focuses on two documents it believes show that the '977 patent was not novel. The first of these is a 1986 article by Petring, *et al.*, entitled "Prevention of Silent Aspiration Due to Leaks around Cuffs of Endotracheal Tubes". (Gropper Decl., Ex. H.) This

article describes tests done with cuffs of different material widths and addresses the continued problem of aspiration during intubation. The cuff described as an "NL cuff," a polyurethane cuff of only 25 microns' width, performed the best in arresting secretion leakage. The authors of the article made the following observation:

> The thickness of the Mallinckrodt cuff is 0.060 mm, whereas the polyurethane cuff on the NL tube is only 0.025 mm. The thinner the cuff, the sharper the foldings and the smaller the channels through which liquid may travel down the trachea. Polyurethane is more pliable and more rubberlike than PVC, and this improves its ability to occlude the trachea tightly.

(*Id.* At 779.)

Although this reference appears to anticipate both the problem (folds allow secretion passage) as well as the solution ("sharper" folds create smaller channels), it does not elaborate in any detail and certainly does not provide a comprehensive solution in the manner that the '977 patent purports to do. Importantly, nowhere does the reference describe draped folds or the process by which the folds arrest fluid passage. And the observation quoted above was essentially an off-the-cuff observation (so to speak) rather than the article's conclusion. Lastly, as K-C notes, the article was prior art considered by the patent examiner, and so Covidien's burden is especially high in this instance. *Hewlett-Packard Co. v. Bausch & Lomb Inc.,* 909 F.2d 1464, 1467 (Fed. Cir. 1990) ("This burden is especially difficult when the prior art was before the PTO examiner during prosecution of the application.") For these reasons, I conclude that although the reference does suggest that the problem of fluid leakage can be solved by thinner materials that create thinner folds, that is not enough to overcome Covidien's heavy burden to show invalidity at this preliminary stage of the proceedings.

A second prior art reference Covidien cites is a 1978 article by Stenqvist, *et al.*, which describes tests of endotracheal cuffs in rabbits. (Gropper Decl., Ex. I.) The goal of the study was

to measure the problems associated with high cuff pressure, and the authors made several conclusions about the appropriate cuff pressure. Nowhere in this article is any discussion of folds, however, much less draped folds designed to thwart secretion flowage. The fact that it involves endotracheal cuffs and the problems associated with high pressure is not enough to anticipate the novelty shown in the '977 patent. Accordingly, I cannot find that Covidien has met its burden to show anticipation.[2]

C. Irreparable Harm

As every defendant in preliminary injunction proceedings points out, injunctive relief is an "extraordinary remedy." It is only appropriate when an injunction is necessary to prevent the kinds of harms that could not be compensated or measured if the matter proceeded in the normal course to a full trial. This principle holds true in patent cases, as the Supreme Court confirmed in *eBay Inc. v. MercExchange, L.L.C.,* 547 U.S. 388, 394 (2006). There, the Court found that the Federal Circuit had erred in applying a general rule favoring the grant of injunctions in cases where infringement and validity had been established. Although that case addressed the equitable standards governing permanent, rather than preliminary, injunctions, there should be no difference in a court's approach to the question of irreparable harm. *Amoco Production Co. v. Village of Gambell, AK,* 480 U.S. 531, 546 n. 2 (1987) ("The standard for a preliminary injunction is essentially the same as for a permanent injunction.") Indeed, a court should be even more reluctant to enter injunctive relief in the *preliminary* context because liability has not been conclusively established.

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[2]For similar reasons, I conclude Covidien has not met its burden to show obviousness. Although the use of thinner materials may have been obvious in light of the prior art, that art does not describe or suggest the process by which the folds inhibit the flow of secretions. Covidien also raised a cursory argument based on indefiniteness, but the fact that the patent does not specifically define "capillary size" does not render the patent indefinite. The specification provides examples and enough context to allow one of ordinary skill in the art to comprehend the term.

K-C's economic expert, Dr. Rozek, testified that K-C would suffer irreparable harm if Covidien were not enjoined from selling its SealGuard products in a number of ways.[3] First, in the period before a trial, K-C would essentially be wasting corporate management resources by competing with a product that infringed its patent and directing its resources towards this litigation. Second, by the time a trial is over K-C will have lost out on significant opportunities to build a customer base. Any lost sales are lost opportunities to sell *other* products as well because there is a significant amount of cross-selling in the industry. Moreover, the development and sales staff it assembled to support its own products might be lost if its sales aren't strong enough. Third, K-C's corporate reputation as an innovator may be harmed. Finally, K-C would lose out on the profits it would have earned, depriving it of the opportunity to invest in research and development, an investment whose fruits are impossible to quantify.

Covidien's expert, Dr. Jerry Hausman, testified that any damages K-C would suffer could all be quantified and are compensable as monetary damages.[4] First, Dr. Hausman rejected the notion that every sale of a SealGuard product was a lost sale for K-C. Because there are a number of differentiated products in the cuff market, the fact that one product might be available does not mean physicians will automatically purchase that one in lieu of K-C's. Even so, he argued persuasively that K-C could recoup its lost sales through a standard award of money damages. As for any sales it lost out on, K-C would be entitled to its lost profits. And for any sales Covidien made that K-C would *not* have made, K-C would be entitled to a reasonable royalty, which can be calculated in the normal course of damages proceedings.

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[3]These opinions are summarized in his declaration, found at Dkt. # 39.

[4]His opinions are also reflected in his declaration, at Dkt. # 23.

I am satisfied that K-C will not suffer irreparable harm, or at least that any such harm at this point is more speculative than real. First, Covidien was persuasive in showing that K-C's R&D program would not be harmed. K-C's United States sales of MicroCuff for 2008 were approximately $850,000, which is a small fraction of K-C's global revenue that is in excess of $19 billion. (Def.'s Ex. 1016.) Any corresponding reduction in R&D would be essentially unnoticeable, and it certainly would not impact the overall R&D position of a company as large as K-C. Nor am I persuaded that there is any significant chance that K-C's reputation would be damaged in the interim. The continued existence of a competitor's product prior to a decision on the merits cannot be expected to count as a black mark against K-C's reputation for innovation or anything else. Moreover, any reputation for innovation K-C may generally enjoy is not contingent on its MicroCuff product because K-C was not the inventor of the '977 patent.

As to the other allegations of irreparable harm, which are based on assertions of waste of corporate resources and market forces, I am not convinced that there is anything particularly special about this case that would justify preliminary injunctive relief. In presumably any infringement case, one could argue that the plaintiff's corporate officers would be expending resources dealing with an infringing competitor's product when they could be engaged more productively. That is true, in fact, of any kind of corporate litigation – the wronged party is forced to divert resources to prosecuting or defending lawsuits. Certainly in the patent context, when a company decides to purchase the intellectual property of another company – or to purchase the company itself – it must factor into the cost the potential that a lawsuit will ensue. But this is not so much irreparable harm as it is the cost of doing business. Moreover, Dr. Rozek's theory that K-C would also lose out on

untold profits from sales of *other* products was largely speculative and not based on any actual sales data or interviews with K-C sales personnel.

Further, I am not persuaded that there is anything atypical about the market for medical products like cuffs that would preclude the award of a reasonable monetary remedy. Although irreparable harm is often found in cases involving head-to-head competitors, the markets at issue here are somewhat different. A large portion of Covidien's business comes from cuffs that have the evacuation feature, which K-C's do not. Similarly, a large portion of K-C's market is pediatric, whereas Covidien is not a participant in the pediatric cuff market. And regardless of whether Covidien infringes the '977 patent or not, I am satisfied that its products are sufficiently different from K-C's products that they are not necessarily head-to-head competitors. Essentially, K-C has largely failed to create a link between lost sales of its own cuffs and sales of infringing cuffs. Even if the injunction is not granted, K-C will be able to continue pursuing its marketing strategy in an effort to create a leadership position in endotracheal cuffs. In the event physicians prefer Covidien's product in the interim, that suggests the public interest would not be served by the grant of an injunction (as discussed below). In short, in the event K-C wins at trial, it should be able to recoup its losses in the form of lost profits and royalties.[5]

D. Public Interest

Finally, a court considering entry of a preliminary injunction must consider whether the public interest would be served or harmed. K-C first suggests that the public interest is always served when valid patents are enforced. Although that argument has some superficial appeal,

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[5]Moreover, it is possible to envision K-C making *more* money under this scenario if Covidien is successful in expanding the market and in selling its own products.

accepting it at face value would render much of the four-part injunction analysis unnecessary because it would make the likelihood of success question dispositive. The Supreme Court in *eBay* was clear in its mandate that courts must undertake the entire analysis before granting injunctive relief, and so I do not place great weight on the public interest in upholding the exclusive rights of patentees.

K-C also argues that there is a public interest in encouraging research and development efforts that lead to patent rights, and that this is fostered by strong enforcement of presumably valid patents. There is some truth to this, of course, as the right to exclude is among the key benefits of a patent. But R&D is also encouraged by the profits and royalties that will ultimately be awarded if K-C is successful, and in this case I find no evidence that K-C's own R&D efforts will be harmed or discouraged.

Covidien's economic expert, Dr. Hausman, interviewed purchasers of cuffs and found that some of them believed the SealGuard cuffs (and other Covidien cuffs) prevented VAP better than other cuffs. Some preferred the evacuation feature on SealGuard or Hi-Lo cuffs, which is not available on K-C's products. Moreover, Covidien has received clearance from the United States Food and Drug Administration to claim two significant advantages of SealGuard and SealGuard EVAC over previous products (not MicroCuff) in reducing the risk of VAP for patients undergoing long-term intubation. (Vannier Decl. ¶ 36, Ex. I at 50.) While MicroCuff apparently offers similar improvements, K-C has not yet received FDA approval to make such a claim.

It is true that MicroCuff, unlike SealGuard, has undergone clinical testing. According to the abstract of a recent clinical study conducted the University of Michigan Health System, use of the polyurethane MicroCuff endotracheal tube was associated with a 43% decrease in VAP over a

conventional polyvinyl chloride tube. (Pl.'s Ex. 1.) But, of course, SealGuard also uses a polyurethane cuff, and according to the only evidence of a head-to-head comparison between the two products, a "bench-top" laboratory test reported in a Covidien technical bulletin, it appears the SealGuard tapered cuff significantly out-performed the MicroCuff tube in the most common size. (Def.'s Ex. 8.) As K-C noted, the test was conducted by Covidien personnel, as opposed to an independent laboratory, and it was not a clinical study. Notwithstanding these deficiencies in Covidien's evidence, however, in the absence of any evidence from K-C that the SealGuard products fail to offer any advantage, it is difficult to find that K-C has met its burden on the public interest question.

Hausman's inquiries to the people who actually make the purchasing decisions are noteworthy. (Hausman Decl., ¶ 30.) Although they all express different preferences, what's clear is that the market for cuffs is evolving and that a number of different approaches are being tried in order to reduce or eliminate VAP, and the SealGuard is one approach physicians are using. If VAP is as serious a problem as both sides claim, there are good reasons to avoid getting in the way of a fluid and broad-based approach to solving the problem. Covidien has cited *Cordis Corp. v. Boston Scientific Corp.,* in which the Federal Circuit upheld the district court's denial of preliminary relief despite its conclusion that the patent was likely infringed and valid. 99 Fed. Appx. 928, 935, 2004 WL 1194246, *6 (Fed. Cir. 2004). Although the case is unpublished, it sets forth a common sense and persuasive rationale eschewing interference with physician choice and preferring a wide array of treatment options. "In this case, a strong public interest supports a broad choice of drug-eluting stents, even though no published study proves the superiority of either Cordis's Cypher or BSC's Taxus stent." *Id.*

The same holds true here. An injunction would mean that some nontrivial number of patients would not be able to receive the treatment their physician preferred. Certainly the fact that a given number of physicians could no longer use their first choice does not necessarily mean that all of their patients would contract VAP. Although the outcome is impossible to measure, I am satisfied that the problem of interfering in patient care in proceedings like this is a real one, and that there is a legitimate public interest in allowing physicians to have as wide a variety of options as is possible. Accordingly, I conclude that the public interest would not be served if I were to grant a preliminary injunction in this case. I further conclude that the balance of all of these factors favors Covidien and the public interest because any potential harm to them outweighs the harm K-C would suffer by the denial of its motion.

For the reasons given above, the motion for a preliminary injunction is **DENIED**. The clerk will place the matter on the calendar for a scheduling conference.

SO ORDERED this 6th day of July, 2009.

s/ William C. Griesbach
William C. Griesbach
United States District Judge